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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/813,326 | 03/30/2004 | Per Gisle Djupesland | 44508-058 | 5109 |
| 21890 | 7590 | 12/27/2010 | EXAMINER | |
| PROSKAUER ROSE LLP One International Place Boston, MA 02110 | | | MENDOZA, MICHAEL G | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3734 | |
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| | | | 12/27/2010 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/813,326 | Applicant(s) DJUPESLAND, PER GISLE | |
| | Examiner MICHAEL G. MENDOZA | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9, 11-18 and 40-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 11-18 is/are allowed.
- 6) ☒ Claim(s) 5, 6, 8, 9 and 40-76 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/22/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 12/13/2010 have been fully considered but they are not persuasive.
2. The applicant argues that Seidel does not seal one of the nostrils and does not teach closing the oropharyngeal velum. The examiner disagrees. A seal is formed when end D is inserted into the nostril. Because end D is inserted into the nostril the end with hinder/prevent escape of gas through the one nostril. As to the limitation of closing the oropharyngeal velum, Seidel teaches exhaling through the mouth to deliver a substance through end D. It would be inherent that the velum be closed since the velum is closed by exhalation through the mouth.
3. As to claims 67-74 rejected by Seidel, the applicant argues that the act of plug a nostril not receiving treatment when using a nasal treatment requiring only one nostril does not read on the limitation of providing a flow resistance to gas flow exiting the other nostril. The examiner disagrees. The act of close one nostril causes resistance to gas flow out of the nostril. As defined in Merriam-Webster Online Dictionary, resistance is an actor or instance of resisting. Closing one nostril resists the gas flow out of the nostril and therefore reads on the limitation. Because one nostril is closed and on nostril is receiving a flow of gas, and positive pressure would be created in the nasal airway. Claims 67-74 also can depend from claims 5, 9, 40, 41, or 45.
4. As to claims 40-42, 47, 52, 55, 67-72, 75, and 76 rejected by Harding, the applicant argues that the act of plug a nostril not receiving treatment when using a nasal

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treatment requiring only one nostril does not read on the limitation of providing a flow resistance to gas flow exiting the other nostril. The examiner disagrees. The act of close one nostril causes resistance to gas flow out of the nostril. As defined in Merriam-Webster Online Dictionary, resistance is an actor or instance of resisting. Closing one nostril resists the gas flow out of the nostril and therefore reads on the limitation.

Because one nostril is closed and on nostril is receiving a flow of gas, and positive pressure would be created in the nasal airway.

5. As to claims 40-47, 52-55, 58, 61-63, 75, and 76 rejected by Keldman et al. in view of Chantrel, the applicant argues that the act of plug a nostril not receiving treatment when using a nasal treatment requiring only one nostril does not read on the limitation of providing a flow resistance to gas flow exiting the other nostril. The examiner disagrees. The act of close one nostril causes resistance to gas flow out of the nostril. As defined in Merriam-Webster Online Dictionary, resistance is an actor or instance of resisting. Closing one nostril resists the gas flow out of the nostril and therefore reads on the limitation. Because one nostril is closed and on nostril is receiving a flow of gas, and positive pressure would be created in the nasal airway. The applicant also argues that the combination of Keldman et al. with Chantrel would have required a fundament change in the operation of the base device. The examiner disagrees. The use of the seal of Chantrel only requires the insertion of the seal into the open end of nasal piece 12. The insertion of the seal in no way changes the operation of the base device. The device will still be inserted into a nostril, and the user would still use exhalation to provide flow.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 5, 6, 8, 52, 55, 58, 59, 60, 63, 64, 65, 66, 75, and 76, are rejected under 35 U.S.C. 102(b) as being anticipated by Seidel 746749.

8. Seidel teaches a method of delivering a substance to the nasal airway of a subject, comprising the steps of: sealing one of the nostrils of a subject to an outlet of a delivery unit such as to prevent the escape of a gas flow through the one nostril; closing the oropharyngeal velum of the subject; and delivering a gas flow around the posterior margin of the nasal septum and out the other nostril of the subject (see figs 1 and 2), wherein the gas flow entraining a substance is provided by actuation of a supply unit (see alternate embodiment fig. 3); wherein the gas flow entraining a substance is separate to an exhalation flow of the subject (fig. 3).

9. As to claims 58-60, 63-65, 75, and 76, see lines 46-58.

10. As to claims 73 and 74, it should also be noted that Seidel fails to teach the claimed range of particle size distribution. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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11. As to claims 67-72, Seidel teaches a device for dispensing an agent through the nostril of a subject. Any type of agent can be used within the device depending on the ailment of the subject. The device of Seidel can be used to treat nasal ailments including the limitations of claims 67-72.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 67-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel.

14. As to claims 67-72, Seidel teaches a device for dispensing an agent through the nostril of a subject. Any type of agent can be used within the device depending on the ailment of the subject. The device of Seidel can be used to treat nasal ailments including the limitations of claims 67-72.

15. As to claims 73 and 74, it should also be noted that Seidel fails to teach the claimed range of particle size distribution. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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16. Claims 40-42, 47, 52, 55, 67-62, 75, 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harding 419942.

17. Harding teaches the claimed method of claims 40-42. It should be noted that Harding fails to teach the claimed range of rate of flow. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

18. As to claims 67-72, Harding teaches a device for dispensing an agent through the nostril of a subject. Any type of agent can be used within the device depending on the ailment of the subject. The device of Harding can be used to treat nasal ailments including the limitations of claims 67-72.

19. Claims 40-47, 52-55, 58, 61-63, 75, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keldman et al. WO 98/53869 in view of Chantrel FR 2638361.

20. Keldman et al. teaches the claimed method of claims 40-42. It should be noted that Keldman fails to specifically teach sealing one nostril.

21. Chantrel teaches a device using a common seal. Therefore it would have been obvious to modify the method of Keldman et al in view of Chantrel for providing a leak tight seal to prevent wasting and proper dispersion of medication. It should also be noted that Keldman et al. fails to teach the claimed range of rate of flow. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

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use the claimed range, since it has been held that where the general conditions of a claims are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

22. As to claim 43 and 44, Keldman/Chantrel teaches the step of using a pressure sensitive valve (pg. 6, lines 5-19)

23. As to claims 45 and 46, Keldman/Chantrel teaches wherein a metered dose of the substance is mechanically dispensed into a deliver chamber (pg. 12, line 27-pg. 13, line 10, dispensed by piercing).

24. As to claim 47, it is well know in the art of inhalers to prevent dry powders from forming agglomerations. Therefore it would have been obvious to one having ordinary skill in the art to modify the dry powder of Keldman/Chantrel to prevent agglomeration for proper dispensing of the dry powder.

25. As to claim 54, It should also be noted that Keldman/Chantrel fails to teach the claimed range of positive pressure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed range, since it has been held that where the general conditions of a claims are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Furthermore, Keldman et al. teaches an adjustable resistor that can be adjusted to the limitations (pg. 3, lines 9-23)

26. As to claims 61 and 62, it should also be noted that Keldman/Chantrel fails to teach the claimed range of particle size distribution. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed range,

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since it has been held that where the general conditions of a claims are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art.

In re Aller, 105 USPQ 233.

27. As to claims 67-72, Keldman/Chantrel teaches a device for dispensing an agent through the nostril of a subject. Any type of agent can be used within the device depending on the ailment of the subject. The device of Keldman/Chantrel can be used to treat nasal ailments including the limitations of claims 67-72.

28. Claims 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keldman et al. in view of Chantrel as applied to claims 40 or 41 above, and further in view of Side et al. 3888252.

29. Keldman/Chantrel teaches the method of claims 40 and 41. It should be noted that Keldman/Chantrel fails to teach a moisture-absorbing element.

30. Side et al. teaches a method with a common moisture-absorbing element.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Keldman/Chantrel to include the use of a moisture-absorbing element to absorb moisture (Desiccant, col. 2, lines 55-67), since it is well know that moisture can cause agglomerations in powdered medications.

31. As to claim 49, the desiccant is a filter for moisture.

32. As to claim 50, anything placed within a flow path will place an amount of resistance to exhalation flow. The desiccant is within the flow path.

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33. Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keldman et al in view of Chantrel as applied to claim 40, 41, and 45 above, and further in view of Butler et al. 5937852.

34. Keldman/Chantrel teaches the device of 40, 41, and 45. It should be noted that Keldman/Chantrel fails to teach providing at least one of a visual or an audible signal.

35. Butler et al. teaches a methods with a common indicator as visual stimulus.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Keldman/Chantrel in view of Butler et al. to indicate when the user is exhaling properly (col. 2 line 67-col. 3, line 1).

Double Patenting

36. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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37. Claims 5-9 and 40-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 252-401 of copending Application No. 10/480582. In the patent, claims 253-280 are dependent on claim 252, claims 282-310 are dependent on claim 281, and claims 312-349 are dependent on claims 311, and claims 351-401 are dependent on claim 350. For double patenting to exist as between the rejected claims and patent claims 253-401, it must be determined that the rejected claims are not patentably distinct from claims 252-401. In order to make this determination, it first must be determined whether there are any difference between the rejected claims and claims 252-401 and , if so, whether those difference render the claims patentably distinct.

38. Claims 5-9 and 40-46 recite "sealing one nostril of a subject", "closing the oropharyngeal velum", and "delivering a gas flow entraining a substance through the outlet at such a driving pressure as to flow around the posterior margin of the nasal septum and out the other nostril of the subject, wherein the gas flow entraining a substance is provided by actuation of a supply unit."

39. It is clear that all the elements of claims 5-9 and 40-46 are to be found in claims 254-257, 284-287, 313-315, 354, 373-375, 390-392, 394, and 395 (as they encompasses the independent claims). The difference between the claims of the application and the claims of the patent lies in the fact that the patent claims includes many more elements and is thus more specific. Thus the invention of the patent claims 252-401 are in effect a "species" of the "generic" invention of claims 5-9 and 40-46. It has been held that the generic invention is "anticipated" by the "species". *In re*

Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 5-9 and 40-46 are anticipated by claims 252-401 of the patent, it is not patentably distinct from the claims.

Allowable Subject Matter

40. Claims 7, 12, and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

41. Claims 11-18 are allowable over the prior art of record.

Response to Arguments

42. Applicant did not argue the previous rejection of the claims, but merely argued the Finality of the last Office Action. Thus the rejections still stand and this action, being the second action using the same grounds of rejection is hereby made FINAL

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./
Examiner, Art Unit 3734

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3776